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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,061

Applicant(s)

BACHUR ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/2004 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 63-65, 67-69, 75 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong (US 4,730,112).

With respect to claim 63, the reference of Wong discloses a system that is capable of detecting growth of microorganisms within a sample in a container. The system includes a laser (16) which is capable of emitting radiation at a substantially single wavelength at which oxygen gas absorbs radiation (See column 5, lines 12-29); a detector (34) adapted to detect a portion of the radiation that passes through the container (30); and a signal analyzer (38) adapted to analyze

Art Unit: 1744

the detected radiation and is capable of indicating the presence a oxygen that absorbs radiation at the emitted wavelength of radiation.

With respect to claim 64, the laser is a monomodal, distributed feedback laser (See Figure 9 and column 5, lines 12-29).

With respect to claim 65, the signal analyzer is capable of indicating the presence of a gas in the sample container that absorbs radiation at a wavelength of approximately 761.5 nanometers (See column 4, lines 63-65).

With respect to claim 67, the analyzer (38) generates a spectrograph (See Figure 9).

With respect to claim , the laser is a laser diode capable of being tuned to emit radiation at a plurality of distinct, substantially single wavelengths (See column 1, lines 21-38).

With respect to claim 92, the system is capable of emitting radiation through the neck of a sample vial. Note neither claim 79 nor claim 92 positively recites the container as part of the positively recited system.

4. Claims 79, 82, 84, 90 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Wrobel et al.(US 3,831,030).

With respect to claim 79, the reference of Wrobel et al. discloses a system that is capable of detecting growth of microorganisms within a sample in a container. The system includes a laser (22) which is capable of emitting radiation at a substantially single wavelength of approximately 2.004 micrometers (See column 1, lines 21-38); a detector (21) adapted to detect a portion of the radiation that passes through the container; and a signal analyzer (25) adapted to analyze the detected radiation and is capable of indicating the presence a gas that absorbs

Art Unit: 1744

radiation at the emitted wavelength of radiation. Note while the reference does not specifically disclose the detection of carbon dioxide at a wavelength of 2.004 micrometers, the disclosed system inherently meets the instant claim language since the disclosed structure is capable of providing and detecting radiation at a wavelength of approximately 2.004 micrometers.

With respect to claim 82, the signal analyzer is capable of indicating the presence of a gas in the sample container that absorbs radiation at a wavelength between 2-6 micrometers.

With respect to claim 84, the analyzer (25) generates a spectrograph (See Figure 6).

With respect to claim 90, the laser is a laser diode capable of being tuned to emit radiation at a plurality of distinct, substantially single wavelengths (See column 1, lines 21-38).

With respect to claim 92, the system is capable of emitting radiation through the neck of a sample vial. Note neither claim 79 nor claim 92 positively recites the container as part of the positively recited system.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1744

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
8. Claims 79, 80, 82-84 and 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the

Art Unit: 1744

gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector.

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas exists in the container, instant claim 79 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al. discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that "Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are "tunable" over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

Art Unit: 1744

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 79 further differs by reciting that a single wavelength of 2.004 micrometers is employed for detecting carbon dioxide within the container.

The reference of Nix et al. discloses that it is known in the art to employ a wavenumber of 4992 (approximately 2.004 micrometers) when detecting for the presence of carbon dioxide within a sealed vessel that can be made of glass or plastic (See column 2, lines 37-58).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a wavelength of approximately 2.004 when detecting for the presence of carbon dioxide within the culture vessel of Sussman et al. for the known and expected result of providing an art recognized means for detecting the presence of carbon dioxide that is independent of the specific material of the transparent container (See column 2, lines 45-48).

With respect to claim 80, the laser suggested by the prior art would be a monomodal laser.

With respect to claims 82 and 83, the system would be capable of determining the presence and/or concentration of carbon dioxide in the container.

Art Unit: 1744

With respect to claim 84, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 90, the laser diodes suggested by the prior art are capable of being tuned.

With respect to claim 91, when detecting a plurality of containers, it would have been obvious to one of ordinary skill in the art to provide a plurality of lasers and sensors, thus eliminating the need to move the containers between a single sensor station.

With respect to claim 92, the system suggested by the prior art above is capable of being used with a sample vial with a neck portion.

With respect to claim 93, if not inherently employed in the system of the modified primary reference, the use of a computer for signal analysis would have clearly been within the purview of one having ordinary skill in the art of IR spectroscopy for the

9. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161) and taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Nix et al. has been discussed above.

The above claims differ by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

Art Unit: 1744

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

10. Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161) and taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Nix et al. has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

Art Unit: 1744

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

11. Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Nix et al.(US 5,473,161) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Nix et al. has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

Art Unit: 1744

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

12. Claims 63-65, 67-69, 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector.

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas is exists in the container, instant claim 63 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al.

Art Unit: 1744

discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that "Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are "tunable" over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy

Art Unit: 1744

while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 63 further differs by reciting that other gas components other than carbon dioxide are detected by the detection system. Specifically, the laser emits radiation at a wavelength at which oxygen absorbs radiation.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Ahnell et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See column 7, lines 34-48).

The reference of Wong discloses that it is known in the art to employ diode lasers to detect oxygen within a gas sample (See column 5, lines 12-59).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide, for example oxygen, within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. The use of a diode laser system as disclosed by Wong would provide an art recognized system for detecting oxygen while providing the benefits associated with a diode laser verses an FTIR system of Sussman as discussed previously.

With respect to claim 64, the laser suggested by the prior art would be a monomodal laser.

Art Unit: 1744

With respect to claim 65, the reference of Wong discloses using a single wavelength of approximately 761.5 nanometers (See column 2, line 65, to column 3, line 13).

With respect to claims 67 and 68, the system would be capable of determining the presence and/or concentration of carbon dioxide in the container.

With respect to claim 69, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 75, the laser diodes suggested by the prior art are capable of being tuned.

With respect to claim 76, when detecting a plurality of containers, it would have been obvious to one of ordinary skill in the art to provide a plurality of lasers and sensors, thus eliminating the need to move the containers between a single sensor station.

With respect to claim 77, the system suggested by the prior art above is capable of being used with a sample vial with a neck portion.

With respect to claim 78, if not inherently employed in the system of the modified primary reference, the use of a computer for signal analysis would have clearly been within the purview of one having ordinary skill in the art of IR spectroscopy for the

13. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112) and taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

Art Unit: 1744

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Wong has been discussed above.

The above claim differs by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

14. Claims 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al. (US 5,155,019) in view of Wrobel et al. (US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al. (US 4,073,691) and Wong (US 4,730,112) and taken further in view of Carr et al. (US 5,888,825).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Wong has been discussed above.

Art Unit: 1744

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

15. Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Wong (US 4,730,112) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Wong has been discussed above.

Art Unit: 1744

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

16. Claims 94-99, 101-103 and 109-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology).

The reference of Sussman et al. discloses a device and method of use for detection of the presence of biological activity in a sealed container utilizing infrared analysis of a gas (carbon dioxide) in at least one container (13). The device includes an energy emitting device (15) adapted to emit an energy signal toward the container wherein the energy signal has substantially a single wavelength band that is equal to a wavelength band at which the desired gas absorbs the energy signal (See column 6, lines 25-33). The device includes a detector (17) and a signal

Art Unit: 1744

analyzer (See column 6, lines 59-68, and Figures 5 and 6) to determine the concentration of the gas and/or whether the gas exists in the container. Also, the container of Sussman et al. is capable of optically transmitting the energy signal from the emitting device to the detector.

While the detection and signal analyzer of the reference of Sussman et al. is able to determine whether the monitored gas exists in the container, instant claim 94 requires that a laser is employed to generate the required energy. Specifically, the reference of Sussman et al. discloses the use of a Nicolet 5-MX FT-IR spectrophotometer for determining the concentration of carbon dioxide within the container which is indicative of the growth or presence of microorganisms within the container (See column 6, lines 59-68, and Figures 5 and 6).

The reference of Wrobel et al. first discloses that "Infrared absorption spectroscopy is a classical method for the detection and quantification determination of numerous gases and vapors" (See column 1, lines 10-12). The reference also discloses that some instruments for IR spectroscopy are inadequate due to narrow absorption linewidths of some gases (See column 1, lines 12-16). The reference of Wrobel et al. also discloses that the use of semiconductor diode lasers in the design of infrared spectrometers is advantageous because they are "tunable" over a wide range of wavelengths and because of their relative simplicity, efficiency and small size (See column 1, lines 21-26).

The reference of Noller discloses that it is known in the art to employ a laser diode when performing spectrophotometric analysis so as to avoid the need for a separate wavelength controller (See column 1, lines 48-66).

Art Unit: 1744

The reference of Veale discloses that the use of tunable diode lasers is advantageous over FTIR spectroscopy because the tunable diode laser has a higher sensitivity than FTIR spectroscopy (See column 1, lines 16-34).

In view of any of these teachings, it would have been obvious to one of ordinary skill in the art at the time the invention to employ an infrared absorption spectroscopy device that employs a laser diode as suggested by any of the references of Wrobel et al. or Noller or Veale in the system of the primary reference of Sussman et al. for the known and expected result of providing an art recognized means for performing classical infrared absorption spectroscopy while providing the benefits associated with the use of a tunable semiconductor diode laser device.

Claim 94 further differs by reciting that other gas components other than carbon dioxide are detected by the detection system. Specifically, the laser emits radiation at a wavelength at which ammonia, hydrogen sulfide, methane or sulfur dioxide absorbs radiation.

The reference of Sussman et al. discloses that while the metabolic product of interest in the examples is carbon dioxide, other metabolically formed gases may be detected (See column 6, lines 25-34).

The reference of Ahnell et al. discloses that it is desirable to detect other gas components other than carbon dioxide when detecting for biological activity within a sealed culture vessel (See column 7, lines 34-48).

The reference of Allen discloses that it is known in the art to employ diode lasers to detect gases including ammonia, methane, hydrogen sulfide and sulfur dioxide within a gas sample (See page 14, first full paragraph and page 33, lines 8-11).

Art Unit: 1744

In view of these teachings, it would have been obvious to one of ordinary skill in the art to modify the system of the primary reference so as to detect gases other than carbon dioxide, for example any of the gases disclosed by the reference of Ahnell, within the vessel by merely providing a wavelength band of light that corresponds to the desired gas to be monitored within the culture vessel. The use of any of the diode laser systems as discussed by Allen would provide art recognized diode lasers capable of detecting the gases suggested by Ahnell while providing the benefits associated with a diode laser verses an FTIR system of Sussman as discussed previously.

With respect to claim 95, the laser suggested by the prior art would be a monomodal laser.

With respect to claims 96-99, the reference of Allen discloses using diode lasers of different wavelengths based merely on the specific gas to be detected. The disclosed diode lasers include wavelengths encompassed by those of claims 96-99 (See pages 14-16 and 33). The specific wavelength employed would have been well within the purview of one having ordinary skill in the art based merely on the specific gas component that is desired to be detected within the gas space.

With respect to claims 101 and 102, the system would be capable of determining the presence and/or concentration of carbon dioxide in the container.

With respect to claim 103, the tunable laser devices suggested by the prior art all include spectrography devices for analyzing the detected portion of the radiation.

With respect to claim 109, the laser diodes suggested by the prior art are capable of being tuned.

Art Unit: 1744

With respect to claim 110, when detecting a plurality of containers, it would have been obvious to one of ordinary skill in the art to provide a plurality of lasers and sensors, thus eliminating the need to move the containers between a single sensor station.

With respect to claim 111, the system suggested by the prior art above is capable of being used with a sample vial with a neck portion.

With respect to claim 112, if not inherently employed in the system of the modified primary reference, the use of a computer for signal analysis would have clearly been within the purview of one having ordinary skill in the art of IR spectroscopy for the

17. Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology) and taken further in view of Waters (US 4,952,498) and Brace (US 5,614,718).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Allen has been discussed above.

The above claim differs by reciting that the IR spectrometry provides an indication of pressure within the culture vessel.

The reference of Waters discloses that a change of pressure within a culture vessel is indicative of the presence of a gas-generating microorganism (See the abstract).

The reference of Brace discloses that it is known in the art to correlate the results of the detection of carbon dioxide concentration using IR spectrometry to pressure of carbon dioxide within the sealed vessel (See column 5, lines 8-25).

In view of these references, it would have been obvious to one of ordinary skill in the art to employ the IR spectrometry results of the primary reference as a means to determine the pressure and/or change of pressure within the sealed culture vessel over time as an alternative means recognized in the art for indicating the presence of a gas-generating microorganism within the vessel.

18. Claims 104-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology) and taken further in view of Carr et al.(US 5,888,825).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Allen has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned in a column/row matrix and/or the that light source and detector are provided within a movable housing that can monitor each of the retained vessels.

The reference of Carr et al. discloses that it is known in the art to position a plurality of sample vessels within a housing (302) and to provide a light source and detector within a movable housing (1024) that can monitor each of the vessels by moving within the matrix of vessels.

Art Unit: 1744

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Carr et al. for the known and expected result of providing a means recognized in the art for providing an incubation environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

19. Claims 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sussman et al.(US 5,155,019) in view of Wrobel et al.(US 3,831,030) or Noller (US 4,857,735) or Veale (US 6,639,678) taken further in view of Ahnell et al.(US 4,073,691) and Allen (Measurement Science and Technology) and taken further in view of Berndt et al.(US 5,518,923).

The combination of the references of Sussman et al. with any of Wrobel et al., Noller, or Veale further in view of Ahnell et al. and Allen has been discussed above.

While the system of Sussman et al. discloses interrogation of a plurality of sample vessels positioned on a movable carousel relative to a fixed sensing system, the reference does not disclose that the sample containers are positioned within a housing with openings.

The reference of Berndt et al. discloses that it is known in the art to employ a housing (30) with a plurality of openings for receiving sample vessels (21). The samples are moved passed a plurality of detection devices (41).

In view of this teaching, it would have been obvious to provide the system of the primary reference in a culture apparatus as disclosed by the reference of Berndt et al. for the known and expected result of providing a means recognized in the art for providing an incubation

Art Unit: 1744

environment for a plurality of sample vessels while allowing non-invasive monitoring of the sample vessels.

Response to Arguments

20. Applicant's arguments filed 11/11/2004 have been fully considered but they are not persuasive.

With respect to the combination of the references of Sussman and Wrobel, Applicants argue that new independent claims 79 would not be met by the combined references because the combination of the references suggests a wavelength of 4.26-4.28 while claim 79 requires a wavelength around 2.004.

In response, new claim 79 has been rejected as being anticipated by Wrobel since the structure of Wrobel is capable of emitting energy at a wavelength around 2.004. Note statements of intended use carry no patentable weight in apparatus-type claims. The new claim has also been rejected over the combination of the references of over Sussman et al. in view of Wrobel et al. or Noller or Veale taken further in view of Nix et al. The reference of Nix et al. suggests the use of a wavelength of approximately 2.004 for detecting the presence of carbon dioxide.

With respect to new independent claims 63 and 94, Applicants argue that the combination of the references of Sussman and Wrobel do not lead to any of the claimed wavelengths for detecting the specific gases of these claims. Applicants argue further that the additional reference of Fraatz would not have led one of ordinary skill in the art to make the proposed combination because i) one of ordinary skill in the art would have employed a FT-IR source rather than a laser source in view of the disclosure of the reference of Sussman, and ii) the

Art Unit: 1744

proposed combination would have been merely been obvious to try and is not suggested by the prior art of record because no one reference suggests the laser system and too many variables would have to be aligned perfectly to achieve a feasible invention.

In response, new claim 63 has been rejected over the combination of the references of Sussman et al. in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell et al. and Wong. New claim 94 has been rejected over the combination of the references of Sussman et al. in view of Wrobel et al. or Noller or Veale taken further in view of Ahnell et al. and Allen. In view of the new grounds of rejection, any of the references of Wrobel, Noller or Veale provide motivation to one having ordinary skill in the art to employ a laser system in place of a FT-IR system for a number of advantages discussed in the references. Furthermore, the reference of Ahnell et al. clearly discloses that the headspace of a culture vial includes gas components that can be detected in addition to carbon dioxide when detecting for the presence of microorganisms within a sample in a culture vial. Finally, the references of Wong and Allen clearly suggest to one of ordinary skill in the art that laser systems of the claimed wavelengths are conventional in the art and would have been capable of being used to detect gases in the headspace of the culture container of the reference of Sussman.

For these reasons, the newly presented claims are rejected over the prior art discussed above.

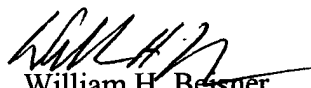
Conclusion

Art Unit: 1744

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB